

Appl. No. 10/796,875
Amdt. dated February 1, 2006
Reply to Office Action of November 1, 2005

PATENT

REMARKS/ARGUMENTS

Claims 1-24 were pending in this application. Claims 1, 10, 17, and 24 have been amended. No claims have been canceled or added. Hence, claims 1-24 remain pending.

Support for the present amendment may be found throughout the specification and original claims, e.g., in Para. [0080]. As such, no new matter enters by way of the present amendment. Entry of the present amendment, and reconsideration of the subject application as amended is respectfully requested.

Double Patenting Rejections

Claims 1, 3, and 7-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over copending applications nos. 10/660,462; 10/426,161; 10/765,318; 11/127,993; 10/119,203; 10/224,263; 10/426,161; 10/460,558; 11/051,345; and 10/401,493. Claims 1, 3, and 4 are also rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over U.S. Patent no. 6,938,618; 5,982,498; 5,551,420; 5,730,122; 5,730,122; 6,062,219; 6,155,257; 6,224,562; 6,315,399; 6,526,973; 6,604,529; 6,587,726; and 6,863,656. These rejections are respectfully traversed for at least the following reason.

The present claims all recite a limitation relating to the timing of the extraction of respiratory gases being at least about 0.1 to about 0.5 of the positive pressure breath to maintain the negative pressure in the thorax. None of the claims of the cited applications or patents include such a limitation. As such, it is submitted that the present claims are patentably distinct over the claims of the cited applications and patents. Withdrawal of these rejections are therefore respectfully requested.

Rejections under 35 U.S.C. § 102(b)

1. Rejection over Biondi

Claims 1, 2, 3, 5-7, 11 and 13 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,377,671 to Biondi *et al.* (hereinafter "Biondi"). This rejection is respectfully traversed for at least the reasons which follow.

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The present claims are directed to a medical method for treating a person suffering from an ailment which can benefit from a negative pressure in the thorax. The method comprises delivering a positive pressure breath to the person; extracting respiratory gases from the person's airway using a vacuum following the positive pressure breath to create an intrathoracic vacuum to lower pressures in the thorax to maintain a negative pressure between 0 mmHg and about -50 mmHg and to enhance blood flow back to the heart; and repeating the steps of delivering positive pressure breaths and extracting respiratory gases to thereby treat the person suffering from the ailment. In accordance with the claims, the respiratory gases are extracted for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to maintain the negative pressure in the thorax.

It is well established that to anticipate a claim, a reference must disclose every element of the claim. *Verdegaal Bros. v. Union Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989).

Whatever else Biondi may disclose, it does not disclose a method for treating a person suffering from an ailment which can benefit from a negative pressure in the thorax, or a method which involves extracting respiratory gases from the person's airway to create an intrathoracic vacuum to lower pressures in the thorax to maintain a negative pressure between 0 mmHg and about -50 mmHg and to enhance blood flow back to the heart. Moreover, Biondi does not disclose a method wherein respiratory gases are extracted for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to maintain the negative pressure in the thorax.

The method and apparatus of Biondi involves increasing the intrathoracic pressure of the patient by introducing a volume of a respiratory gas under a positive pressure into the lungs of the patient during the ventricular systolic portion of the cardiac cycle. Following the introduction of the respiratory gas into the lungs under a positive pressure, the method of Biondi includes reducing the pressure of the respiratory gas and thereby reducing intrathoracic pressure of the patient. This reduction in pressure is accomplished by extracting, during the diastolic portion of the cardiac cycle, under subambient or substantially ambient pressure, a portion of the volume of the respiratory gas from the lungs. However, Biondi does not teach or provide any

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suggestion with regard to the duration of the extraction phase, or the desirability of creating and maintaining a negative pressure in the thorax.

Although Biondi may mention in passing “subambient” pressures, there is no specific teaching regarding the desirability of maintaining negative pressures in the thorax, or any benefit of such pressures in the treatment of subjects suffering from any particular ailments. In fact, Biondi exemplifies only atmospheric and positive intrathoracic pressures, *e.g.*, see Fig. 3C. Further, Biondi teaches that ventilatory function may result in an interference with cardiac function as a result of the positive pressure applied to the lungs and generated by the expanding lungs. This positive pressure, if applied during the diastolic or filling phase of the cardiac cycle, increases the pressure around the heart and compresses the veins returning blood to the heart, thereby preventing the heart from filling and ejecting adequately.

As such, Biondi teaches the importance of timing the respiratory gas introduction and extraction portions of the ventilatory cycle so as to be synchronous with portions of the cardiac cycle. However, Biondi is completely silent with regard to any specific correlation between negative intrathoracic pressures and the treatment of subjects or the increase of blood flow, much less the importance of maintaining a negative intrathoracic pressure. Instead, Biondi focuses on the effects of positive pressure during the diastolic phase of the cardiac cycle. Absent such teachings, Biondi does not disclose each and every element of the claims. For at least these reasons, withdrawal of this rejection is respectfully requested.

2. Rejection over Alferness

Claims 17, 18, 21, 23, and 24 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,349,015 to Alferness *et al.* (hereinafter “Alferness”). This rejection is respectfully traversed for at least the reasons which follow.

The present claims are directed to a device for lowering intrathoracic pressures. The device repeatedly extracts respiratory gases from the patient’s lungs and airway to create and periodically maintain a negative intrathoracic pressure; regulates the extraction of respiratory gases within the patient’s lungs and airway; and delivers a positive pressure breath to periodically provide inspiration of respiratory gases. In accordance with the claims, the

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extraction of respiratory gases from the patient's lungs and airway are regulated for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to thereby maintain the negative intrathoracic pressure.

Alferness, on the other hand, discloses an apparatus for cardiopulmonary resuscitation (CPR), including manually-actuable bellows adapted to be placed on a patient's chest and an airway apparatus adapted to be placed in proximity to the patient's airway. The CPR apparatus functions to pressurize the patient's lungs at the same time that the patient's chest is being compressed by force transmitted through the bellows, thereby increasing the patient's intrathoracic pressure. During bellows decompression, intrathoracic pressure decreases due to removal of force from the patient's chest and to depressurization of the bellows, whereby the heart and lungs refills with blood from the circulatory system and the lungs deflating.

Whatever else Alferness does disclose, Alferness does not teach or suggest a device which regulates the extraction of respiratory gases, nor does Alferness teach or suggest regulating the extraction of respiratory gases for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to thereby maintain the negative intrathoracic pressure. As mentioned above, Alferness refers to a decrease in intrathoracic pressure due to the heart and lungs refilling with blood from the circulatory system and the lungs deflating. Such a descriptions indicates that Alferness in fact teaches a passive process rather than an active, regulated process as recited in the present claims.

Absent such teachings, Alferness does not disclose each and every element of the claims. For at least these reasons, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

1. Rejection over Biondi

Claims 4, 8-10, 12, and 14-16 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Biondi. This rejection is respectfully traversed for at least the reasons which follow.

The Examiner acknowledges that Biondi does not disclose the ranges of different system parameters, such as breath delivery time and date, vacuum pressure and intrathoracic

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pressure levels. However, in support of the rejection, the Examiner alleges that it would have been obvious to one of skill in the art to optimize the most effective variables to achieve optimal results, such as reducing intracranial pressures. Again, Applicants respectfully traverse.

Initially, Biondi does not teach or suggest to one of skill in the art a correlation between negative intrathoracic pressures and a reduction in intracranial pressures. As such, it is submitted that one of skill would not be motivated, based on the teachings of Biondi, to optimize the method of Biondi to achieve results related to reducing intracranial pressures. Instead, as discussed above, Biondi teaches the importance of timing the respiratory gas introduction and extraction portions of the ventilatory cycle so as to be synchronous with portions of the cardiac cycle. However, Biondi is completely silent with regard to any specific correlation between negative intrathoracic pressures and the treatment of subjects or the increase of blood flow, much less the importance of maintaining a negative intrathoracic pressure.

As such, whatever else Biondi may disclose, absent a suggestion of the desirability of maintaining a negative intrathoracic pressure, one of skill in the art would not identify the specifically claimed system parameters as result effective variables to optimize in the manner claimed. *See, e.g.* MPEP 2144.05(II)B. Based on the teachings of Biondi, one of skill in the art would look to optimize the timing of inspiration and expiration cycles around the cardiac cycle rather than around maintaining a negative intrathoracic pressure. As such, one of skill in the art would not be motivated to modify the teachings of Biondi so as to arrive at the present invention. As such, withdrawal of this rejection is respectfully requested.

2. Rejection over Alferness

Claim 22 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Alferness. This rejection is respectfully traversed for at least the reasons which follow.

The Examiner acknowledges that Alferness does not disclose the actuating pressure ranges. However, in support of the rejection, the Examiner alleges that it would have been obvious to one of skill in the art to arrive at the claimed pressure ranges based on the teachings of Alferness. Again, Applicants respectfully traverse.

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As discussed above, Alferness does not teach or suggest a device which regulates the extraction of respiratory gases, nor does Alferness teach or suggest regulating the extraction of respiratory gases for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to thereby maintain the negative intrathoracic pressure. Alferness refers to a decrease in intrathoracic pressure due to the heart and lungs refilling with blood from the circulatory system and the lungs deflating. Such a descriptions indicates that Alferness in fact teaches a passive process rather than an active, regulated process as recited in the present claims. As such, based on the teachings of Alferness, one of skill in the art would not be motivated to modify the CPR device of Alferness in a manner so as to maintain negative intrathoracic pressures, much less actuate in negative pressure ranges. As such, one of skill in the art would not be motivated to modify the teachings of Alferness so as to arrive at the present invention. As such, withdrawal of this rejection is respectfully requested.

3. Rejection over Alferness in view of Biondi

Claims 19 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Alferness in view of Biondi. Whatever else Alferness and Biondi may disclose, as discussed above, neither reference discloses or suggests maintaining a negative intrathoracic pressure, much less regulating the extraction of respiratory gases for a time that is at least about 0.1 to about 0.5 of the positive pressure breath to thereby maintain the negative intrathoracic pressure. As such, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,



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